ABBOTT

Global Medical Services

Abbott Laboratories
Global Medical Services
200 Abbott Park Road AP34-2
Abbott Park, Illinois 60064-6186
Office: 1-800-633-9110
Fax: 1-847-938-0644

November 2, 2004

COPY

[redacted]

To Whom it May Concern;

Abbott Laboratories has received an adverse event report in which your product, Levothyroxine Sodium Tablet®™, was identified as a suspect drug. We are forwarding this information to your company for your use in complying with the FDA regulations for the reporting of spontaneous and clinical adverse events and ICH Guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

Patient information:
[redacted]

Phone number: [redacted]

The patient experienced increased fatigue and feeling cold with Levothyroxine Sodium Tablets.

Should you wish to contact us, please call 1-800-633-9110

Sincerely,

Ray Labayo, RN, BSN
Abbott Laboratories
Medical Services Specialist
Global Pharmaceutical and Research Department

CONFIDENTIAL

ABBOTT

Global Medical Services

Postmarketing Safety
Dept. R422, AP34-2S
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6008

No Adverse Event Memo
Re: Synthroid

Date: November 2, 2004

On 02 Nov 2004, we received a phone call from [redacted] who stated that she was experiencing adverse events with Synthroid. When the patient was contacted, the suspect medication was identified as Levothyroxine Sodium tablets which are manufactured by [redacted]. The patient said she was recently switched to the Levothyroxine Sodium tablets from Synthroid and was experiencing increased fatigue and feeling cold. There was no adverse event with Synthroid. No further action was required.

Ray Labayo RN, BSN 02 Nov 2004
Post-Marketing Safety Post marketing safety Analyst

Pamela Rieb
Post-Marketing Safety Manager

USER MUST VERIFY CURRENCY OF PRINTED SOP/GUIDELINE AT TIME OF IMPLEMENTATION

Global Medical Services, Pharmacovigilance
Global Pharmaceutical Research and Development

Medical Information and Product Safety

RECORD OF CONTACT

DATE: 11/2/04 TIME: 8:30 (am) pm

☐ Adverse Reaction

☐ AEGIS Database search

Product: Synthroid

Reporter Name: [redacted]

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Patient ☐ Abbott Rep* ☐ Other_____

Reporter Address: _____
Street

_____ [redacted]
City State Zip

Telephone: ([redacted] [redacted] *Territory_____

Patient identifiers: _____ Sex _____ Age _____ Initials

ADVERSE EVENT(S): _____

SUMMARY OF DISCUSSION:

This individual called this AM & stated she was on Synthroid & had been switched to another levothyroxine product ([redacted]). Since switching she had experienced increased fatigue & feeling cold. She was instructed to contact her MD & the appropriate company to report these AE's. I understand PMS is collecting reports of this nature, [redacted] on this specific product.

Front Desk Staff: [redacted] Date 11/2/04
Signature

R422-03-F-001
Effective Date 22Dec2003